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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations for oxytetracycline injectable solutions. The regulations for oxytetracycline injectable solutions are also being revised to conform to a current format. These changes are being made to improve the organization and readability of the regulations.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

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SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 19, 2003 (68 FR 54804), § 522.1660a (21 CFR 522.1660a) was added to reflect the approval of a 300-milligram (mg)/milliliter (mL) oxytetracycline injectable solution under NADA 141–143. At this time, we are redesignating and amending §§ 522.1660 (21 CFR 522.1660) and 522.1660a as §§ 522.1660a and 522.1660b, respectively. These sections are also being revised to conform to a current format. These changes are being made to improve the organization and readability of the regulations.

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This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Sections 522.1660 and 522.1660a are redesignated as §§ 522.1660a and 522.1660b, respectively, and new § 522.1660 is added to read as follows:

§ 522.1660 Oxytetracycline injectable solutions.

■ 3. Newly redesignated § 522.1660a is amended by revising paragraphs (b) and (c), by redesignating paragraph (d) as paragraph (e), by revising newly redesignated paragraph (e), and by adding new paragraph (d) to read as follows:

§ 522.1660a Oxytetracycline injection, 200 milligrams/milliliter.

(a) * * *

(b) *Sponsors.* See Nos. 000010, 000069, 011722, 053389, 055529, 057561, 059130, and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Special considerations.* When labeled for the treatment of anaplasmosis or anthrax, labeling shall also bear the following: "Federal law restricts this drug to use by or on the order of a licensed veterinarian."

(e) *Conditions of use*—(1) *Beef cattle, dairy cattle, and calves including prerumenative (veal) calves*—(i) *Amounts and indications for use*—(A) 3 to 5 mg per pound of body weight (mg/lb BW) per day (/day) intramuscularly, subcutaneously, or intravenously for treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp., and anthrax caused by *Bacillus anthracis.*

(B) 5 mg/lb BW/day intramuscularly or intravenously for treatment of anaplasmosis caused by *Anaplasma marginale*, severe foot-rot, and advanced cases of other indicated diseases.

(C) 9 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical, for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*, or where retreatment for anaplasmosis is impractical.

(D) 9 to 13.6 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical or for treatment of infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis.*

(E) 13.6 mg/lb BW intramuscularly or subcutaneously as a single dosage for control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (Pasteurella) haemolytica.*

(ii) *Limitations.* Exceeding the highest recommended level of drug per pound of bodyweight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site may result in antibiotic residues beyond the withdrawal time. Rapid intravenous administration in cattle may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes. Discontinue treatment at least 28 days prior to slaughter. Not for use in lactating dairy animals.

(2) *Swine*—(i) *Amounts and indications for use*—(A) Sows: 3 mg/lb BW intramuscularly once, approximately 8 hours before farrowing or immediately after completion of farrowing, as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli.*

(B) 3 to 5 mg/lb BW/day intramuscularly for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona.*

(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

(ii) *Limitations.* Administer intramuscularly. Do not inject more than 5 mL per site in adult swine. Discontinue treatment at least 28 days prior to slaughter.

■ 4. Newly redesignated § 522.1660b is amended in paragraph (e)(1)(ii) by removing "milliliter" and by adding in its place "mL", by removing paragraph (e)(2)(ii), by redesignating paragraph (e)(2)(iii) as new paragraph (e)(2)(ii) and

removing "milliliter" and by adding in its place "mL", and by revising paragraph (e)(2)(i) to read as follows:

§ 522.1660b Oxytetracycline injection, 300 milligrams/milliliter.

* * * * *

(e) * * *

(2) *Swine*—(i) *Amounts and indications for use*—(A) Sows: 3 mg/lb BW intramuscularly once, approximately 8 hours before farrowing or immediately after completion of farrowing, as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli.*

(B) 3 to 5 mg/lb BW/day intramuscularly for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli,* pneumonia caused by *Pasteurella multocida,* and leptospirosis caused by *Leptospira pomona.*

(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

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